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APPLICATION
FOR
UNITED STATES LETTERS PATENT

TITLE: METHODS AND DEVICES FOR REMOVING AN
OBSTRUCTION FROM A BLOOD VESSEL

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METHODS AND DEVICES FOR REMOVING AN OBSTRUCTION FROM A BLOOD VESSEL

BACKGROUND OF THE INVENTION

5 The present invention is directed to methods and devices for removing obstructions from blood vessels. The device may be used to retrieve and remove clots and other biological obstructions. The device may also be used to retrieve embolic coils and the like which have been misplaced or have migrated to an undesirable location.

10 One such obstruction removal device is disclosed in U.S. Patent No. 5,895,398 which is hereby incorporated by reference. The device has an expandable engaging member which is introduced into the blood vessel to engage the obstruction for removal.

 The present invention is directed to additional devices and methods for
15 removing obstructions in a blood vessel.

SUMMARY OF THE INVENTION

 In accordance with the present invention, device and methods for removing obstructions are provided. In a first aspect of the invention, an obstruction removal device is
20 provided which has an obstruction engaging element extending from an insertion element. The engaging element is movable from a collapse position to an expanded position. The engaging element forms coils having varying diameter wherein the coils at a distal portion are larger than coils at an intermediate portion. The distal portion forms a relatively closed structure which prevents the obstruction, or any part thereof, from migrating downstream.

25 The distal portion is expanded distal to the obstruction while the proximal portion engages and holds the obstruction.

 In another aspect of the present invention, another obstruction removal device is provided which has at least one closed loop and preferably two closed loops. The closed
30 loop provides an advantage when advanced through a catheter or sheath in that the closed loop produces opposing radial forces on the catheter or sheath through which the loop is advanced. In this manner, the obstruction removal device can be advanced more easily

through the catheter or sheath to prevent binding or kinking of the device during advancement. In a preferred embodiment, the obstruction removal device has two loops of varying diameter with the distal loop having a larger diameter. Each of the loops lie in a plane with the planes of the two loops preferably being perpendicular to one another.

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In another aspect of the invention, another obstruction removal device is provided which has wound sections formed by one or more filaments which are separated by sections substantially free of the filaments. The intermittent wound sections provide discrete portions where the obstruction can be engaged. In an embodiment, the wound sections can
10 slide on the core element to provide flexibility when advancing the obstruction removal device. The wound sections and sections free of filament are preferably about 1-5 mm long. The obstruction removal device preferably has at least three wound sections and more preferably at least five wound sections.

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In still another aspect of the invention, another obstruction removal device is provided which has alternating large and small diameter portions. In a preferred embodiment, the obstruction removal device has at least four large diameter sections and three smaller diameter portions. The alternating large and small diameter portions may help to engage certain types of obstructions and can also help to prevent parts of the obstruction from
20 breaking off and migrating downstream.

Any of the obstruction removal devices described herein may also be used with a source of power coupled to the obstruction removal device for use as described below. The source of power may simply produce a positive or negative charge or may be an RF
25 energy source. The source of power may be used to help the obstruction removal device penetrate and engage the obstruction and may also be used to adhere the obstruction to the obstruction removal device as will be described. In a preferred embodiment, a negative charge is provided when advancing the obstruction removal device into the obstruction and a positive charge, or RF energy, is supplied to adhere the device to the obstruction.

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The devices of the present invention may be manufactured in any suitable manner. In another aspect of the present invention, the obstruction removal device has a core element surrounded by a sheath. A strand, preferably about four strands, are positioned

between the core element and the tube. The strand and the tube prevent any part of the obstruction removal device from breaking free should the core element fail. The strand and tube will hold the obstruction removal device together even if the core element breaks. The sheath is preferably flexible so that the sheath can undergo much larger deflections than the
5 core element.

The obstruction removal devices of the present invention may also be advanced through a guide catheter having a flow restricting element which is preferably a balloon but may be any other suitable structure. The flow restricting element is expanded to
10 reduce blood flow through the obstructed vessel to minimize the likelihood that the obstruction will migrate downstream.

These and other advantages of the invention will become apparent from the following description, drawings and claims.

15 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a system for removing an obstruction.

Figure 2 shows the obstruction removal device in a collapsed condition.

Figure 3 shows the obstruction removal device with a distal portion of the obstruction removal device expanded.

20 Figure 4 shows the obstruction removal device with a proximal portion expanded to engage an obstruction.

Figure 5 shows another obstruction removal device.

Figure 6 shows yet another obstruction removal device.

Figure 7 shows still another obstruction removal device.

25 Figure 8 is an end view of the obstruction removal device of Figure 7.

Figure 9 is an exploded view showing a method of constructing an obstruction removal device.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1-4, a system 2 for removing an obstruction is shown.
30 A guide catheter 4 is advanced to a location proximal to an obstruction. When accessing the cerebral vasculature, for example, the guide catheter 4 is often positioned in the carotid or vertebral artery. Of course, the guide catheter 4 may not be necessary or may be positioned in

any other suitable location depending upon the location of the obstruction. The guide catheter 4 preferably has a flow restricting element 6 which restricts or even stops blood flow through the vessel as described below. The flow restricting element 6 is preferably a balloon 5 coupled to a source of inflation fluid 7 which is used to inflate the balloon 5.

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An obstruction removing device 8 is advanced through the guide catheter 4 to the obstruction. A microcatheter 10 may also be positioned within the guide catheter 4 to deliver the obstruction removing device 8 further into the vasculature. The obstruction removing device may be advanced by itself through the microcatheter 10 or may be contained within a sheath 12 which is advanced through the microcatheter 10. A source power 14 may also be coupled to the obstruction removal device 8 for use in the manner explained below. The power source 14 may simply produce a positive or negative charge or may be an RF or other suitable power source.

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The obstruction removing device 8 has an engaging element 16 extending from an insertion element 18. The engaging element 16 is movable from a collapsed position (Fig. 2) to an expanded position (Figs. 3 and 4). When the engaging element 16 is contained within the sheath 12 or microcatheter 10, the engaging element 16 is in a relatively straight configuration. The engaging element 16 has a distal portion 20, which forms a relatively closed structure, which can catch or trap the obstruction, or any part thereof, to prevent migration of the obstruction or part thereof. The engaging element 16 has a proximal portion 22 which is formed with smaller coils than the distal portion 20. The proximal portion 22 engages the obstruction as described below.

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The engaging element 16 preferably has a number of markers 23, 25, 27 which provide an indication as to how much of the engaging element 16 extends from the sheath 12 or microcatheter 10. For example, markers 23, 25, 27 may indicate when the engaging element 16 is $\frac{1}{2}$, $\frac{3}{4}$ or fully exposed. In this manner, the user may quickly advance the engaging element 16 through the sheath 12 or microcatheter 10 without inadvertently exposing and advancing the engaging element 16 out of the sheath 12 or microcatheter. The markers 23, 25, 27 can also be used to provide a controlled diameter of the engaging element 16 since the diameter of the engaging element 16 is known for the various positions corresponding to the markers 23, 25, 27. The markers 23, 25, 27 may also

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be used to size the vessel in which the engaging element 16 is positioned by observing when the engaging element 16 engages the vessel walls and determining the size of the engaging element 16 using the markers 23, 25, 27.

5 The insertion element 18 is preferably made of a superelastic material or stainless steel having a diameter of 0.004 to 0.038 inch and preferably about 0.010 inch. Although the insertion element 18 is preferably a solid, elongate element, the insertion element 18 may take any other suitable structure such as a hollow tube. The engaging element 16 is preferably made of a superelastic material, such as nitinol, and has a diameter of
10 0.005-0.018 inch, more preferably 0.005-0.010 inch and most preferably about 0.008 inch. The engaging element 16 has a rounded, atraumatic tip 24 to prevent damage to the vessel and facilitate advancement through the vessel, microcatheter 10 and/or sheath 12. A radiopaque wire 26, such as platinum ribbon 28 having a width of 0.004 inch and a thickness of 0.002 inch, is preferably wrapped around the engaging element 16 to improve radiopacity.

15 The device 8 is preferably self-expanding but may also be expanded with an actuator 29. The actuator 29 is preferably a thin filament which is tensioned to move the device 8 to the expanded position. An advantage of the invention is that the filament 29 extends through the same lumen as the device 8 thereby minimizing the overall size of the device. It is understood that throughout discussion of the devices and methods herein that any
20 of the devices may be expanded using the actuator 29 rather than being self-expanding without departing from the scope of various aspects of the invention.

 The device 8 may also include a cover 9 which extends between adjacent coils.
25 The cover 9 may be a number of individual strands 11 which extend between the coils or may be an elastic membrane which covers the coils. The strands 11 are preferably elastic to stretch when the device 8 is expanded.

 Use of the obstruction removing device 8 is now described. The guide
30 catheter 4 is introduced into the patient and delivered proximal to the target vessel such as to the carotid or vertebral artery. The microcatheter 10 is then advanced through the guide catheter 4 further into the vasculature to a position proximal to, within or distal to the obstruction. The obstruction removal device 8 is then advanced through the microcatheter 10

either by itself or pre-loaded within the sheath 12. The obstruction removal device 8 is then advanced to the obstruction. Before advancing the obstruction removal device 8 further, the flow restricting element 6 on the guide catheter 4 is expanded to reduce and even stop flow through the vessel. Stopping flow in the vessel may help prevent the obstruction, or any parts thereof, from migrating downstream. Reducing flow through the vessel may also reduce the likelihood that the obstruction is disrupted by a combination of flow and the obstruction removal device 8.

The obstruction removal device 8 is then placed into the obstruction and preferably through the obstruction. The engaging element 16 is then advanced out of the microcatheter 10 or sheath 12 to permit the distal portion 20 of the engaging element 16 to expand at a location beyond the obstruction. In this manner, the relatively closed distal portion 20 prevents the obstruction, or any part thereof, from migrating downstream. The proximal portion 22 is then advanced out of the sheath 12 or microcatheter 10 so that the smaller coils of the proximal portion 22 engage the obstruction as shown in Fig. 4.

Referring to Fig. 5, another obstruction removal device 8A is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8A has a first section 30 with larger diameter coils than a second section 32. A third section 34 also has larger coils than the second section 32 with the second section 32 positioned between the first and third sections 30, 34. The obstruction removal device 8A may have a number of alternating small and large sections 30, 32, 34 which can enhance the ability of the obstruction removal device 8A to engage various obstructions. In the preferred embodiment of Fig. 5, the obstruction removal device 8A has four large sections 32, 34 with relatively large coils and three sections 30 having smaller coils.

The obstruction removal device 8A may be used in any suitable manner to engage the obstruction. For example, the microcatheter 10 or sheath 12 may be advanced through the obstruction and then retracted to expose the obstruction removal device 8A. The obstruction removal device 8A is then retracted into the obstruction to engage the obstruction. The obstruction removal device 8A may be rotated when moved into the obstruction to take advantage of the generally helical shape of the obstruction removal device. The obstruction removal device 8A may also be used to engage the obstruction by simply retracting the

microcatheter 10 or sheath 12 with the obstruction removal device 8A expanding within the obstruction. Finally, the engaging element 16A may be exposed and expanded proximal to the obstruction and then advanced into the obstruction. When advancing the obstruction removal device 8A into the obstruction, the user may also twist the obstruction removal device 8A to take advantage of the generally helical shape. The alternating large and small sections 30, 32, 34 enhance the ability of the engaging element 16A to engage varying shapes and sizes of obstructions.

Referring to Fig. 6, still another obstruction removal device 8B is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8B has the insertion element 18 with an engaging element 16B extending therefrom. The engaging element 16B forms a helical coil 38 with a generally frustoconical shape, however, the engaging element 16B may take any other shape without departing from the scope of the invention including any shape disclosed in this application or any patent incorporated by reference herein.

A filament 40, preferably a radiopaque filament, is wrapped around the engaging element 16B. The filament 40 is wrapped somewhat loosely around the engaging element 16B so that the filament 40 provides additional surface area to engage the obstruction. The filament 40 forms a wound section 42, and more preferably at least five wound sections 42, which are separated by substantially exposed sections 44 of the engaging element 16B. The wound and exposed sections 42, 44 may be 1-5 mm long. Stated another way, the wound and exposed sections 42, 44 are at least 1 mm, more preferably at least 3 mm long, and no more than 8 mm long. The wound sections 42 may be formed by a single filament 40 which extends continuously between the wound sections 42 or may be formed by independent filaments 40 at each wound section 42 which are attached to the engaging element 16B.

The wound sections 40 may be movable along the engaging element 16B to provide flexibility when advancing the obstruction removal device 8B through small and tortuous vessels. The movable wound sections 40 may also allow different parts of the obstruction removal device 8B to grip different parts of the obstruction to hold the obstruction together or engage different parts of the obstruction. The obstruction removal device 8B is

used in substantially the same manner as the other obstruction removal devices described herein. The obstruction removal device 8B has a handle 41 with a lead screw 43 which engages threads 55. The handle 41 is rotated to advance and retract the engaging element 16B.

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Referring to Fig. 7, still another obstruction removal device 8C is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8C has an engaging element 16C, which forms a first closed loop 50, and a second closed loop 52. The first loop 50 is preferably somewhat larger than the second closed loop 52 with the first loop 50 having a diameter of about 1.5-8.0 mm and the second loop 52 having a diameter of about 1.5-6.0 mm. A tip 54 extends from the first loop 50 for a distance of about 5 mm. A radiopaque element 56, such as platinum ribbon, is preferably wrapped around the loops 50, 52 to improve radiopacity and to enhance the ability of the engaging element 16C to hold the obstruction. The radiopaque element 56 also may provide advantages when engaging an obstruction in a manner similar to the obstruction removal devices described above with reference to Fig. 6.

An advantage of the obstruction removal device 8C is that the loops 50, 52 exert substantially equal and opposing forces on the sheath 12 or microcatheter 10 through which the obstruction removal device 8C is advanced. In this manner, kinking or binding of the obstruction removal device 8C during advancement can be minimized or reduced altogether. Referring to the end view of Fig. 8, the first and second loops 50, 52 preferably lie in first and second planes 58, 60, respectively, which are preferably perpendicular to one another.

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Referring to Fig. 9, an exploded view of a construction of the obstruction removal device 8, 8A, 8B, 8C is shown. A tube 62, which is preferably a thermoplastic polymer such as polyester or urethane is positioned over a core element 64. As mentioned above, the core element 64 is preferably a superelastic or stainless steel element at either the insertion element 18 or the engaging element 16 (Figs. 2-7). A reinforcing strand 66 is trapped between the tube 62 and the core element 64 to reinforce the obstruction removal device. The strand 66 is preferably small and has a diameter or thickness of less than 0.005 inch, more preferably less than 0.0001 inch, so that the overall size of the obstruction removal

device is not increased significantly with use of the strand 66. The strand 66 may be made of any suitable material including VECTRAN made by Celanese Acetate LLP or DACRON or KEVLAR which are both manufactured by Dupont. VECTRAN is a thermoplastic multifilament yarn spun from a liquid crystal polymer.

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The strand 66 provides a degree of safety in that the strand 66 and tube 62 together prevent any part of the obstruction removal device from breaking free from the rest of the device. The tube 62 will resist breaking since it is more flexible than the core element 64 and can undergo larger deflections and displacements without breaking. In a preferred
10 embodiment, 2-8 strands 66, preferably about 4 strands 66, are used. The overall size of the device is also relatively small with the outer diameter of the resulting structure being no more than 0.020 inch and more preferably no more than 0.012 inch.

The power source 14 may be also be used with any of the obstruction removal
15 devices in the following manner, however, the methods and devices of the present invention may, of course, be practiced without the power source 14. As mentioned above, the power source 14 may simply produce a charge at the engaging element 16 or may be a source of RF energy. In one particular method of the present invention, the power source 14 produces a negative charge while advancing the engaging element 16 through the obstruction. The
20 negative charge may aid in passing the engaging element 16 through the obstruction and may help to dissolve part of the obstruction. The power supply is then changed to produce a positive charge to adhere the obstruction to the engaging element 16. Alternatively, the power source 14 may be an RF energy source, which delivers RF to the engaging element 16 which also adheres the obstruction to the engaging element 16 and may help provide a
25 controlled penetration into the obstruction. The obstruction is then removed by moving the obstruction into the guide catheter 4, which is then withdrawn to remove the obstruction. Use of the power source 14 is particularly useful when the obstruction is a biologic structure such as a clot.

30 While the above is a description of the preferred embodiments of the invention, various alternatives, substitutions and modifications may be made without departing from the scope thereof, which is defined by the following claims. Thus, the preferred embodiments should not be taken as limiting the scope of the invention. For

example, although all of the obstruction removal devices described herein are self-expanding structures, the obstruction removal devices may also have actuating mechanisms for moving the engaging element between the expanded and collapsed positions. Furthermore, the present invention is directed to a number of separate inventions and each of these inventions
5 may be claimed independently of one another. Each feature, aspect and advantage of the invention may be claimed independent of one another without departing from the scope of the invention. For example, use of the power source 14 is independent of the using the intermittent wound sections 42 but may be used with any of the devices and methods described herein. Thus, the invention does not include a single essential feature, aspect or
10 advantage and the invention should not be limited as such. Finally, the preferred dimensions, materials and methods of manufacture described for any of the embodiments is equally applicable for other embodiments.